## REMARKS

Claims 1-6, 10-22, 24-26, 28-29 and 34-35 are pending in the application.

Claims 30, 32 and 33 correspond to unelected species. Claim 23 was withdrawn from further consideration by the Examiner in the Office Action mailed 12 November 2008. Claims 7-9, 27 and 31 were cancelled in our response filed February 12, 2009. Claims 34 and 35 were added in our response filed February 12, 2009.

No amendments to the claims are being made in the present response.

**35 USC 103 Rejections in view of Fixel and Birbeau**

Claims 1-5, 8-12, 14-22, 31, 34 and 35 were objected to under 35 USC 103 as being unpatentable over Fixel (US 3,990,116) in view of Birbeau (FR 2,724,309).

The Examiner acknowledges that Fixel fails to disclose that the flexible member is smaller than the bore and that it is free to float and move.

Specifically, as explained in our previous response, the following features of claim 1 of the present application are not disclosed in Fixel:

(a) the cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity; and

(b) the flexible component is free to move laterally and rotationally within the cavity.

The Examiner expressed the opinion that these features are disclosed in Birbeau and so it would be obvious for the person of ordinary skill in the art to combine an oversized bore as taught by Birbeau with the device of Fixel.

Applicant respectfully disagrees. Fundamentally, the Applicant submits that these missing features are not, in fact, found in Birbeau and that any incorporation of such features in Fixel would be highly detrimental to Fixel, as will now be explained.

Birbeau is a French document, so we enclose a copy of its English language abstract, for the Examiner's convenience. [Appendix A]

According to the Examiner's analysis, Birbeau teaches the use of an implantable joint comprising first and second attachment components 4 and 6. Whilst this is an understandable interpretation based on the drawings, unfortunately the drawings are ambiguous, and the Applicant respectfully submits that this is not a correct interpretation of Birbeau. The English abstract of Birbeau describes component 18 as "an anchoring element (18)... designed to be inserted and anchored in a bone medullary canal".

Furthermore, page 4, lines 15 to 17 of Birbeau states:

> "La figure 1 montre l'implantation d'une prothese d'articulation 2 entre une premiere phalange 4 de l'index d'une main et un os metacarpien 6 correspondant."

This translates as:

> "Figure 1 shows the implantation of an articulation prosthesis 2 between a first phalanx 4 of the index finger of a hand and a corresponding metacarpal bone 6."

The French word "os" means "bone" and a phalanx is "a bone in a finger or toe". A dictionary extract confirming these definitions is enclosed. [Appendix 2]

Looking now at Fig. 1 in the light of the information given in the English abstract, it is clear that the item referenced 4 immediately surrounding the anchoring element 18 in the Birbeau drawing, which was interpreted by the Examiner as being part of the implantable joint, is in fact part of the patient's bone, and is not part of the implantable joint.

Therefore, the components 4 and 6 to which the Examiner referred are both part of the patient's bone. They are not part of the implantable joint 2.

In support of the rejection, the Examiner has also stated that "the member 8 is smaller than bores 22 and 24". Again, the Applicant respectfully submits that the drawings are ambiguous on this point and this interpretation is also incorrect when the drawings are considered in conjunction with the description. The bores of present claim 1 are the bores of the implantable joint. However, bores 22 and 24 in Birbeau are not bores of the implantable joint. Firstly, in support of this is the proof above that components 4 and 6 are parts of the bone. It is clearly shown in Fig 1 that the bores 22 and 24 are in the bone. Thus, they are not in the implant (18, 20). Turning to the description for further support we read on page 4, lines 21 to 25 of Birbeau:

> "Ces deux tiges 10, 12 sont recues dans des evidements 14, 16 de deux forreaux d'ancrage 18, 20 ancres respectivement dans un canal medullaire 22 de la premiere phalange 4 et dans un canal medullaire 24 de l'os metacarpien 6."

This translates into English as:

> "These two stems 10, 12 are received in bores 14, 16 of the two anchoring elements 18, 20 that are respectively anchored in a medullary canal 22 of the first phalanx 4 and in a medullary canal 24 of the metacarpal bone 6".

Hence, it is clear that the bores 22 and 24 are actually the medullary canals in the bone, and they are not bores of the implantable joint, as stated by the Examiner. Therefore the bores 22 and 24 disclosed by Birbeau do not disclose the claimed features of the bores in the implantable joint of the present invention.

In support of the rejection, the Examiner also states that "the bore shown in Figures 2 to 5 is larger than member 30". However, this is also not correct. Although this is not self-evident from the drawings alone, reference 30 does not actually designate a member in the sense of claim 1. Reference number 30 actually designates the inner cylindrical surface of the anchoring element 18 ("la surface cylindrique 30 dudit forreau [18]", described at page 5, lines 10 to 11 of Birbeau).

Therefore, Applicant respectfully submits that the Examiner's analysis of Birbeau is not correct because of the misinterpretation of Birbeau and its drawings.

For the Examiner's assistance, the disclosure of Birbeau will now be explained. A copy of Birbeau's drawings, marked-up in English, is enclosed for the Examiner's convenience. [Appendix 3]

Birbeau discloses two anchor components 18, 20, which are installed in the bone on either side of a finger joint. The referenced items 4, 6 in the drawings are parts of the patient's bone, and are not parts of the implant.

The anchor components 18, 20 each have a central bore 14, 16 therethrough.

An insert member comprising an articulation body 8 having two stems/legs 10, 12 is also provided and, according to page 4, lines 21 to 25, the stems 10, 12 are received within bores 14, 16 within the anchor components 18, 20. Fig 1 and Fig 5 show the stems 10, 12 of the insert member are a tight fit within the bores 14, 16 of the anchor components 18, 20.

The English language abstract also confirms the presence of two side channels 32 (see Figs 2 and 3).

Fig 3 shows that the stem 10 is located inside the cylindrical surface 30 of the bore 14 (the stem 10 is shown as a faint line inside the cylindrical surface 30/side channels 32). It is clear from viewing Figs 1 and 3 together that the stem 10 is the radially innermost feature in Fig 3. Furthermore, this is stated on page 6, lines 12 to 14:

> "Sur la figure 3, on a represente en trait fin la tige 10 munie de deux doigts lateraux de positionnement de la prothese cooperant avec les rainures 32".

This translates as:

> "In Fig 3, the stem 10 is shown in fine lines, provided with two lateral positioning fingers of the prosthesis, which co-operate with the side channels 32".

Fig 5 also shows the stem 10 (in fine lines) inside the cylindrical surface 30 - note the lateral positioning fingers of the stem 10 which protrude into the side channels 32 and which prevent rotation of the insert member within the bore 14. Hence it is very clear from both Figs 3 and 5 that the insert member is a tight fit within the bore 14 and cannot rotate.

Accordingly, the Examiner's statement that Birbeau shows an apparatus having an oversized bore that will inherently allow lateral and axial movement, is not correct. Actually, the stems 10, 12 are a very close fit within their respective bores 14, 16, and it is obvious from Fig 3 that no lateral or rotational movement is possible.

Indeed, the side channels 32 of Birbeau are there to specifically prevent ANY possible rotation of the insert member. Furthermore, no longitudinal movement is possible, because the stems 10, 12 will be forced to the ends of the bores 14, 16 in use, as is shown in Fig 5. The insert is not "freely floating" in the sense of present claim 1 because Birbeau's anchor components do not bear directly upon each other and, instead, the insert (the articulation body 8 and stems 10, 12) is fully load-bearing.

Considering again the two missing features from Fixel:

(a) the cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity; and

(b) the flexible component is free to move laterally and rotationally within the cavity.

we can now see that neither of these features is disclosed in Birbeau.

Firstly, there is no disclosure in Birbeau that the articulation body 8 and stems 10, 12 are flexible. Hence, there is no clear and unambiguous disclosure of the presence of a flexible component.

Secondly, the cavity formed by the bores 14, 16 is shorter than the flexible component 8, 10, evidenced by the fact that, in Fig 1, the stem 10 protrudes from the cavity and the articulation body 8 (also part of the insert) is fully outside the cavity. Hence, even if the articulation body and stems 8, 10, 12 could be considered to be a flexible component, such a flexible component has no possibility of moving axially within the cavity. It is, instead, rammed hard up against the ends of the bores 14, 16.

Thirdly, the flexible component has no possibility of moving laterally within the cavity. See in particular Fig 3 of Birbeau, where the contours of the stem 10 closely matches the contours of its bore.

Fourthly, the flexible component has no possibility of moving rotationally within the cavity. See in particular both Figs 3 and 5 of Birbeau, which show the lateral fingers in the side channels 32 specifically in order to prevent rotation.

Hence, the person of ordinary skill in the art could not combine Fixel with Birbeau to arrive at the present invention, because none of the claimed features missing from Fixel are actually disclosed in Birbeau. Reading Birbeau together with Fixel would, instead, reinforce Fixel's teaching that the insert member should be fully load-bearing instead of freely-floating, and that no axial, lateral or rotational movement should be allowed. The person of ordinary skill in the art is therefore led much further away from the present invention by consulting Birbeau.

Furthermore there are many reasons why such changes, even arrived at without the motivation of Birbeau, would be extremely detrimental to Fixel, as follows:

1. Flexible component is movable axially, laterally and rotationally within cavity.

In the present invention, the flexible component is free to move axially, laterally and rotationally within the cavity. This allows the pivot axis (around which the first and second components move relative to one another) to be movable relative to the device, thereby creating a "sloppy hinge" between the first and second components, as disclosed at page 7, lines 20 to 31 of the present application as filed. This permits the first and second components to move axially relative to one another while moving in relative rotation and flexion/extension or in medial/lateral directions. The ability to move axially while rotating, deviating laterally, and flexing or extending enables the replacement joint to move in a similar fashion to the natural joint it is replacing.

In contrast, Fixel is concerned with knee and finger joints (see column 1, lines 6 to 11). Natural knee and finger joints move principally in one plane (forwards and backwards between a bent position and a stretched position). However, natural finger and knee joints

also permit very subtle lateral and rotational movements of around 2 to 5 degrees. Fixel's joint is fixed, both laterally and rotationally. The support member 11 is fixed in rotation with respect to the leaf springs 18, which is fixed in rotation with respect to the support member 12 by the snug interference fit of the leaf springs 18 in the cavities 15, 16. Hence, absolutely no rotation is permitted by Fixel. Thus, the subtle rotational movements of the natural finger joint cannot be achieved by Fixel.

Furthermore, leaf springs, by definition, allow bending only forwards and backwards and in no other direction. Hence, by the choice of leaf springs, it is impossible for Fixel's device to bend in two directions simultaneously to mimic a natural joint.

Yet another advantage of axial, lateral and rotational freedom of movement is that, with the present invention, the flexible component does not always move in response to relative pivoting of the first and second components, and when it does bend, it does not bend as much as the first and second components. For example, since the claimed flexible component has axial, lateral and rotational clearance, small movements of the first and second component do not cause the walls of the first and second components even to contact the flexible component. Therefore, the flexible component is not put under either stress or tension when subtle movements of the first and second component occur.

When large movements occur, again because of the clearance, the flexible component bends through a smaller angle than the first and second components. For example, the first component might pivot at 60 degrees with respect to the second component, but this may only cause the flexible component to bend at 50 degrees.

In contrast, with Fixel, every single movement of the support members 11, 12 relative to each other MUST trigger bending of the stack of leaf springs 18, because there is no axial, lateral or rotational clearance. Furthermore, when the support members 11, 12 pivot through 60 degrees, the leaf springs 18 must also pivot through 60 degrees.

Hence, due to the freedom of movement axially, laterally and rotationally, the flexible component of the present invention undergoes less movement than Fixel's stack of leaf springs, and when it does move, it is bent through a smaller angle. This is an advantage

because the flexible component of the present invention undergoes less wear, and therefore has increased longevity.

However, the person of ordinary skill in the art, wishing to improve Fixel's device would never wish to modify Fixel's device based on Birbeau or any other document, such that the stack of leaf springs 18 could move axially, laterally and rotationally within the cavities 15, 16.

The stack of leaf springs 18 has to work together, with each spring being aligned with its neighbours. However, if there was excess room in the cavity for lateral movement or rotation, the stack of leaf springs 18 would cease to be an integrated stack, since some would protrude to the left and right. This could then cause irregular deformation of the springs. Given sufficient room, some of the leaf springs could even come out of the stack completely.

Hence, amended claim 1 is non-obvious over Fixel, because the skilled person would immediately see that modifying Fixel's device such that the stack of leaf springs 18 could move axially, laterally and rotationally within the cavities 15, 16 could never work in the context of Fixel's device.

2. Oversized Cavity

In the present invention, the cavity is longer than the flexible component so that the flexible component can move axially within the cavity, which allows the flexible component to be non-load bearing in respect of axial loads. This has two advantages: (1) the flexible component will not wear out so quickly; and (2) the flexible component is protected from being damaged by the cut bone ends.

Considering the first advantage, the Fixel design involves direct axial loading on the flexible component. Joints of the human body undergo high forces, which are created by muscles pulling on tendons. These forces can be of the order of several hundred Newtons. A typical force for gripping an article might be in the order of 200 Newtons.

In Fixel, all of this high loading is taken by the stack of leaf springs 18. This is the reason why Fixel relies on a whole stack of springs instead of just a single spring; column 3,

lines 40 to 43 explains the advantage in the Fixel system that there is no single point of stress or fatigue in the individual leaves and the tension forces are distributed and diffused throughout the total system. The person of ordinary skill, wishing to improve the strength/life span of Fixel's replacement joint, might find it obvious to add some more leaf springs to the stack, or to form the leaf springs from an even stronger material, in keeping with this expressed advantage of the Fixel system. However, there is no hint or teaching to redesign Fixel based on Birbeau or any other document, such that the leaf springs 18 are no longer load-bearing, or so that the cavity is longer than the leaf springs. This would destroy the alignment and integrity of the stack, and would be a retrograde step.

Considering the second advantage, in order to insert any replacement joint into a human body, a surgeon needs to cut out the damaged bone surfaces as a first step. This exposes freshly cut bone edges. The surgeon then installs the replacement joint. This is true for both the replacement joint of the present invention, and of the joints of Fixel, Vitale and Huebner.

After the surgery, when the patient moves the replacement joint in their normal life, the flexible component can come into contact with the sharp bone edges which were cut by the surgeon, and this abrades or otherwise damages the flexible component.

However, the person of ordinary skill in the art would never seek to modify Fixel such that the cavity was made longer than the flexible component, because the leaf springs 18 in Figs 1 and 2 of Fixel are the ONLY means of carrying axial loads between the first and second support members 11, 12. Column 3 lines 3 to 43 describes the principle that the stack of leaf springs 18 works as a cantilever beam, bridging the joint and thereby spacing the support members 11, 12 apart. As shown in Figs 1 and 2, the support members 11, 12 do not contact each other and are in fact spaced apart by a considerable gap. There is no hint or suggestion to completely divert from this principle into the idea that the leaf springs 18 should NOT function as a cantilever beam and should not space the support members 11, 12 apart. Concerning Fig 5, this embodiment is described as incorporating the Fig 1 spring joint, so this confirms that also in Fig 5, the stack of leaf springs 18 is load-bearing in respect of axial loads and spans a gap between the support members 32, 34. Furthermore, in Fig 5,

the cavity in component 32 is drawn considerably shorter than upwardly protruding part of the leaf springs 18. Hence, both the description and the drawing of Fig 5 supports that the cavity is shorter than the leaf springs 18.

Furthermore, the person of ordinary skill in the art would not seek to protect the flexible component from damage by modifying Fixel's design so that the cavity was made longer than the leaf springs 18, because Fixel has already solved the problem of protecting the leaf springs 18 in a different way. For example, in Fig 2, the exposed portion of the stack of leaf springs 18 is protected by interfitting hollow hemispherical members 20, 21. Hence, having already been presented with this alternative way of protecting the leaf springs 18, there is no need for the person of ordinary skill to design any further around a problem which has already been solved.

**Non-obviousness - Summary**

As explained above, amended claim 1 has at least two differentiating features not present in Fixel:

1. The flexible component being free to move laterally and rotationally within the cavity; and

2. The cavity formed by the bores in the first and second components is longer than the flexible component so that the flexible component can move axially within the cavity.

Neither of these features are present in Birbeau, which instead discloses an intermediate component 8, 10, 12 - not disclosed as "flexible" - that is located within bores 14, 16 in first and second components 18, 20 in a close fit, such that lateral, rotational and axial movement are all prevented. Furthermore, Birbeau's cavity is considerably shorter than the intermediate component (8, 10, 12), which therefore cannot be freely-floating within the cavity. Hence, Birbeau leads the person of ordinary skill in the art further away from the present invention.

In any case, the person of ordinary skill in the art would never wish to make the necessary modifications to Fixel's device to arrive at the present invention, whether or not inspired by Birbeau, because such modifications do not even make sense in the context of Fixel.

If Fixel's leaf springs were free to rotate laterally and rotationally within the cavity, the stack of leaf springs would become disordered and the leaf springs would become damaged. Hence, the person of ordinary skill in the art would never modify Fixel's device such that the leaf springs could move laterally and rotationally within the cavity.

Furthermore, the person of ordinary skill in the art would not modify Fixel such that the cavity was longer than the flexible component, because if he wished to improve the strength, he would use more springs or stronger springs, and if he wished to limit the damage to the springs and increase longevity, he would use the protective spherical cover of Fig 2. However, he would find no inspiration or motivation to completely redesign Fixel such that, against the core teachings of Fixel, the stack of leaf springs was no longer load-bearing, the cavity was formed longer than the springs, and the springs no longer provided a cantilever beam bridge to transfer axial loads between the two support members.

Hence, amended claim 1 is non-obvious over Fixel, even in view of Birbeau.

35 USC 103: Rejection of dependent claims

The Examiner rejected claims 2-5, 8-12, 14-22 and 31 as unpatentable over Fixel in view of Birbeau. Please note that claims 8, 9 and 31 have previously been cancelled.

The Examiner rejected claims 6 and 7 as unpatentable over Fixel modified by Birbeau in view of Vitale (US 5,683,466). Please note that claim 7 has previously been cancelled.

The Examiner rejected claims 24 to 29 as unpatentable over Fixel modified by Birbeau in view of Huebner (US 5,702,472). Please note that claim 27 has previously been cancelled.

Claims 2-6, 10-22, 24-26, 28 and 29 are all dependent on claim 1. As noted above, claim 1 is novel and nonobvious over the combination of Fixel and Birbeua. As such,

without prejudice to their individual merits, each of these claims are also novel and non-obvious, at least by virtue of their dependenc from claim 1.

Independent claims 34 and 35

The Examiner rejected claims 34 and 35 as unpatentable over Fixel in view of Birbeau.

Independent claim 34 shares the novel and non-obvious features of claim 1 that the flexible component is free to move axially, laterally and rotationally within the cavity.

Independent claim 35 shares the novel and non-obvious feature of claim 1 that the cavity formed by the bores in the first and second components is longer than the flexible component.

Hence, claims 34 and 35 are also novel and non-obvious for the same reasons as explained above with respect to claim 1.

**Request for Allowance**

Based on the foreogin, reconsideration and withdrawal of the rejections of all the claims in the present application is respectfully requested. It is thus believed that the application is now allowable and notification to this effect is earnestly solicited.

Should the Examiner have any questions or comments regarding Applicants' amendments or response, he is asked to contact Applicants' representative Gregory Lavorgna at (215) 988-3309.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573.

Respectfully submitted,

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Encs: English language abstract of Birbeau
French-English dictionary extract re "phalange"
Marked-up copy of Birbeau's drawings with English annotations

**APPENDIX 1**

# Bone joint prosthesis anchoring element

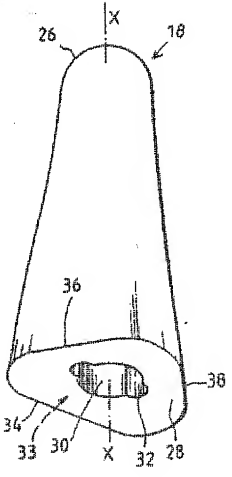
**Patent number:** FR2724309 (A1)
**Publication date:** 1996-03-15
**Inventor(s):** BIRBEAU FRANCOIS
**Applicant(s):** PROCERATI [FR]
**Classification:**
**- international:** ***A61F2/42;*** **A61F2/42;** (IPC1-7): A61F2/30; A61B17/16; A61F2/42
**- european:** A61F2/42H
**Application number:** FR19940010980 19940914
**Priority number(s):** FR19940010980 19940914

**Cited documents:**

- FR2692776 (A1)
- GB2045085 (A)
- EP0064277 (A1)
- DE9310268U (U1)

Abstract of **FR 2724309 (A1)**

The anchoring element (18), which is elongated in shape and designed to be inserted and anchored in a bone medullary canal, has a lateral surface with at least one portion (33) shaped to prevent it from rotating inside the bone. The anti-rotation portion has a flat surface e.g. forming a portion of a triangle or polygon with rounded corners. The interior of the anchoring element is shaped to receive a shank connected to the joint prosthesis e.g. in the form of a central aperture (30) with two side channels (32). The anchoring element's outer surface is coated with a layer of titanium.



**APPENDIX 2**

| | | |
|---|---|---|
| **1.** Subject Field(s)<br>Animal Anatomy<br>Bones and Joints | Domaine(s)<br>Anatomie animale<br>Os et articulations | |
| **phalanx**<br>CORRECT | **phalange**<br>CORRECT, FEM | |
| phalange<br>CORRECT | | |
| **DEF –** A bone in a digit of a foot; a bone in a finger or toe. | **DEF –** Chacun des os longs qui soutiennent les doigts et les orteils (des tétrapodes) | |
| **2008-05-27** | | |
| **2.** Subject Field(s)<br>Bones and Joints | Domaine(s)<br>Os et articulations | Campo(s) temático(s)<br>Huesos y articulaciones |
| **phalanx**<br>CORRECT | **phalange**<br>CORRECT, FEM | **falange**<br>CORRECT, FEM |
| phalanx<br>LATIN | phalanx<br>LATIN | |
| **DEF –** Any of the bones of the fingers or toes.<br>**OBS –** The plural of "phalanx" is "phalanges". | **DEF –** Chacun des petits os qui constituent le squelette des doigts et des orteils et qui sont au nombre de deux dans le pouce et le gros orteil, de trois dans les quatre autres doigts et orteils. | |
| **KEY TERM(S)**<br>– phalanges | | |
| **2004-09-28** | | |
| **3.** Subject Field(s)<br>Bones and Joints | Domaine(s)<br>Os et articulations | |
| **proximal phalanx**<br>CORRECT | **phalange proximale**<br>CORRECT, FEM | |
| phalanx proximalis<br>LATIN | 1re phalange<br>CORRECT, SEE OBS, FEM | |
| | première phalange<br>CORRECT, SEE OBS, FEM | |
| | phalange<br>CORRECT, SEE OBS, FEM | |
| | phalanx proximalis<br>LATIN | |
| **DEF –** Any one of the bones that articulate with the metacarpal bones (in the fingers) or with the metatarsal bones (in the toes) and with the phalanx media (except in | **OBS –** Les os des doigts et des orteils sont constitués par les deux phalanges (petits os courts articulés) du pouce et du gros orteil ainsi que les trois phalanges des | |

| | | |
|---|---|---|
| the thumb and the great toe).<br><br>**OBS –** The plural of "phalanx" is "phalanges". | quatre derniers doigts et orteils. Ils sont numérotés de haut en bas ou d'arrière en avant. La première, la phalange proximale, la phalange moyenne, (dite aussi phalange intermédiaire, deuxième phalange ou phalangine) et la phalange distale (dite aussi phalangette ou phalange unguéale [près de l'ongle]).<br><br>**OBS –** Ancienne nomenclature : 1re phalange; première phalange; phalange.<br><br>**OBS –** 1re : «re» est en exposant. | |
| **2000-03-08** | | |
| **4.** Subject Field(s)<br>Paleontology<br>Systematic Botany (General) | Domaine(s)<br>Paléontologie<br>Botanique systématique (Généralités) | |
| **phalange**<br>CORRECT | **phalange**<br>CORRECT | |
| **DEF –** A bundle of stamens united by filaments | **OBS –** (...) étamines polyadelphes ou soudées en phalanges ou falsceaux. | |
| **1998-03-24** | | |

**APPENDIX 3**

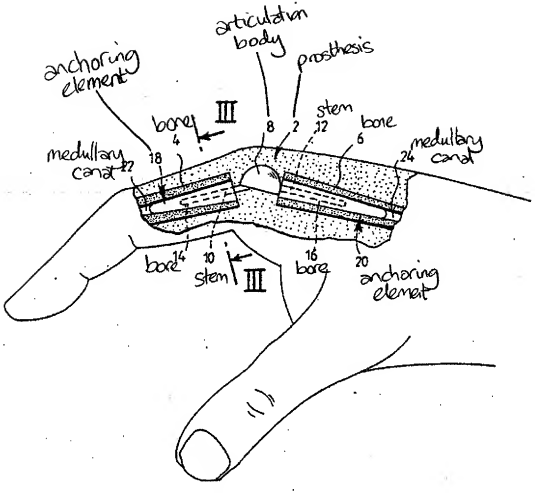

anchoring element
articulation body
prosthesis
bore
4
III
8
2
stem
12
bone
6
medullary canal
22
18
24
medullary canal
bore
14
10
stem
III
16
bore
20
anchoring element

FIG. 1

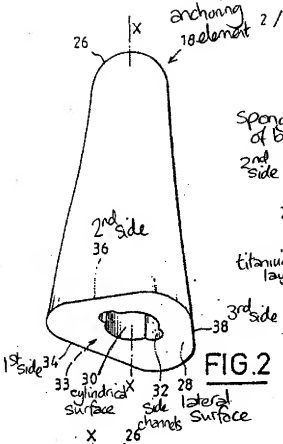



FIG.2

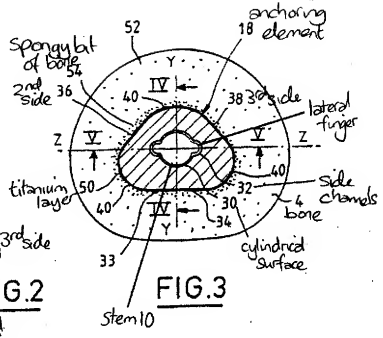



FIG.3

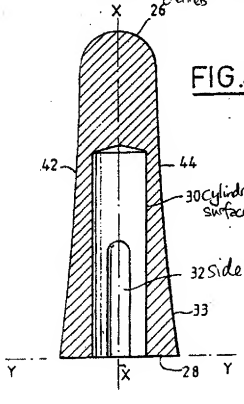



FIG.4

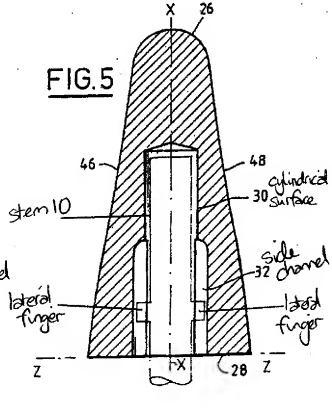



FIG.5